K043427

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DuraGen II *Dural Regeneration Matrix*
510(K) SUMMARY

Submitter's name and address:

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536 USA

Contact person and telephone number:

Diana M. Bordon
Manager, Regulatory Affairs,
(609) 936-2240

Date: December 10, 2004

Name of the device:

Proprietary Name:	DuraGen II
Common Name:	Dural Regeneration Matrix
Classification Name:	Dura Substitute, Product Code 84GXQ Class II Regulation Number 882.5910

Substantial Equivalence:

DuraGen II *Dural Regeneration Matrix* is substantially equivalent in function and intended use to the currently marketed DuraGen Plus™ *Dural Regeneration Matrix* (K032693).

Intended Use:

DuraGen II *Dural Regeneration Matrix* is indicated as a dura substitute for the repair of dura mater.

Device Description:

DuraGen II *Dural Regeneration Matrix* is an absorbable implant for repair of dural defects. DuraGen II *Dural Regeneration Matrix* is an easy to handle, soft, white, pliable, nonfriable, porous collagen matrix with a mechanically strengthened collagen component. DuraGen II *Dural Regeneration Matrix* is supplied sterile, nonpyrogenic, for single use in double peel packages in a variety of sizes. DuraGen II *Dural Regeneration Matrix* may be applied using either onlay or suturing technique depending on clinical need and surgeon preference.

Conclusion:

Valid scientific evidence through physical property testing provide reasonable assurance that DuraGen II *Dural Regeneration Matrix* is safe and effective under the proposed conditions of use, and is, with respect to intended use and technological characteristics, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2005

Ms. Diana M. Bordon
Manager, Regulatory Affairs
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K043427
Trade/Device Name: DuraGen II Dural Regeneration Matrix
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura substitute
Regulatory Class: II
Product Code: GXQ
Dated: December 10, 2004
Received: December 13, 200

Dear Ms. Bordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043427

Device Name: DuraGen II *Dural Regeneration Matrix*

Indications For Use:

DuraGen II *Dural Regeneration Matrix* is indicated as a dura substitute for the repair of dura mater.

Prescription Use _X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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